## NOT FOR PUBLICATION

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

PROMOTE INNOVATION LLC,

Plaintiff,

Civil Action No. 11-607 (JAP)

v.

**OPINION** 

ORTHO-MCNEIL PHARMACEUTICAL, : LLC and ORTHO-MCNEIL-JANSEN : PHARMACEUTICAL, INC., :

Defendants.

rendants.

## PISANO, District Judge:

Before the Court is a motion to dismiss filed by Defendants Ortho-McNeil

Pharmaceutical, LLC and Ortho-McNeil-Jansen Pharmaceuticals, Inc. Plaintiff Promote

Innovation, LLC opposes the motion. For the reasons that follow, Defendants' motion will be granted.

Plaintiff filed a *qui tam* relator complaint on behalf of the United States under Section 292 of the Patent Act, 35 U.S.C. § 292. Section 292 provides, in relevant part:

- (a) ... Whoever marks upon, or affixes to, or uses in advertising in connection with any unpatented article, the word "patent" or any word or number importing that the same is patented for the purpose of deceiving the public . . . [s]hall be fined not more than \$500 for every such offense.
- (b) Any person may sue for the penalty, in which event one-half shall go to the person suing and the other to the use of the United States.

35 U.S.C. § 292(a)-(b). According to Plaintiff's Second Amended Complaint ("Complaint"), the patent at issue expired no later than October 4, 2005, and Defendants continued to mark their Retin-A Micro products (the "Products") with the patent number after the patent expired. The

Complaint also asserts that a package insert for the Products bears a copyright date of 2006, indicating that Defendants revised the package insert after the patent expired but nonetheless included the patent number on the package insert. The Complaint continues to claim that Defendants are "large, sophisticated companies" that retain "sophisticated legal counsel," and that Defendants knew that the patent had expired and that it was a false statement to include the patent number on its Products.

Rule 9(b) of the Federal Rules of Civil Procedure requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." The Federal Circuit recognized in *In re BP Lubricants USA Inc.*, 637 F.3d 1307 (Fed. Cir. 2011), that Rule 9(b)'s particularity requirement applies to false marking claims under Section 292, such as the claims in the instant case. *See id.* at 1309. The Federal Circuit also noted that "the bar for proving deceptive intent in false marking cases is particularly high,' requiring that relator show 'a purpose of deceit, rather than simply knowledge that a statement is false." *Id.* at 1313 (quoting *Pequignot v. Solo Cup Co.*, 608 F.3d 1356, 1362-63 (Fed. Cir. 2010)). "[A]lthough 'knowledge' and 'intent' may be averred generally . . . under Rule 9(b), '[Federal Circuit] precedent, like that of several regional circuits, requires that the pleadings allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind." *Id.* at 1311 (quoting *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009)).

Plaintiff's pleadings fail to satisfy the requirements of Rule 9(b) as articulated in *BP Lubricants*. As in that case, the Complaint before the Court asserts only various allegations that

Defendants were sophisticated companies that knew a patent had expired and nonetheless

marked their Products with its number. That Defendants were "large, sophisticated companies"

and therefore knew or should have known that a patent expired is nothing more a conclusory allegation that is "not entitled to an assumption of truth at any stage in litigation." *Id.* at 1312 (citing *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1952 (2009)).

Plaintiff's only allegation of fact is that Defendants revised a package insert after the expiration of the patent. Plaintiff asserts that this is a fact from which the Court can reasonably infer that Defendants knew the patent was expired, but nonetheless chose to continue to mark its Products with it. The inclusion of the expired patent number on the package insert after a single revision, however, is a mere statement "where the relationship between factual falsity and state of mind is not . . . apparent" enough that the falsity of the statement automatically shows scienter. See id., 637 F.3d at 1312 (citing Merck & Co. v. Reynolds, 130 S. Ct. 1784, 1793) (2010)). Therefore, the Court agrees with several other district courts that have determined that a packaging revision does not, alone, evidence a purpose of deceit. See Brinkmeier v. BIC Corp., 733 F. Supp. 2d 552, 563 (D. Del. 2010) ("To the extent that plaintiff is arguing that [defendant] had knowledge that the patents were expired because the packaging of these products was updated following patent expiration, this argument fails to prove [defendant] had intent to deceive the public."); Herengracht Group LLC v. Intelligent Products, Inc., 2011 WL 938995, \*4 (S.D. Fla. 2011) (holding that packaging that contains an expired patent number, though revised after its expiration, is not evidence of intent to deceive); Shizzle Pop, LLC v. Wham-O, Inc., 2010 WL 3063066, \*4 (C.D. Cal. 2010) ("[C] reating new packaging does not create a reasonable inference that Defendant knew the . . . patent had expired.").1

Also before the Court is a motion by Plaintiff to file a sur-reply in response to Defendants' contention that the package insert does not qualify as a "marking" of the Products under Section 292. The Court, however, will dismiss Plaintiff's Complaint without relying or ruling on this particular aspect of Defendants' argument. Accordingly, Plaintiff's motion to file a sur-reply will be denied as moot.

Accordingly, because the only factual allegation in Plaintiff's Complaint fails to satisfy the pleading requirements of Rule 9(b), the Court must grant Defendants' motion to dismiss.<sup>2</sup>

Defendants also contend that their motion should be granted with prejudice because Plaintiff has already amended its pleadings twice to respond to various motions filed by Defendants. Plaintiff responds that the two amendments were irrelevant to the issue before the Court and therefore leave should be granted to amend. The Court will not grant Plaintiff leave to amend its pleadings. Defendants have, from their first motion to dismiss, Docket Entry no. 7, filed May 26, 2010, provided Plaintiff with notice that its pleadings may be deficient for failure to plead intent and for failing to meet the requirements of Rule 9(b). After Plaintiff first amended its complaint, mooting the original motion to dismiss, Defendants again moved to dismiss, reiterating their argument that Plaintiff's pleadings were deficient under Rule 9(b). See Mot. to Dismiss, Docket Entry no. 18, filed July 10, 2010. On August 12, 2010, Defendants filed notice with the Court of recent court decisions that supported their argument under Rule 9(b). After a second amended complaint, Defendants filed another motion to dismiss with the same Rule 9(b) argument. See Mot. to Dismiss, Docket Entry no. 40, filed Nov. 5, 2010. Finally, after a transfer of venue to the District of New Jersey, Defendants filed the instant motion. Plaintiff has long been on notice and frequently reminded of its deficient pleadings. Nothing in the pleadings nor in its papers opposing the motion to dismiss indicates that Plaintiff could allege any facts that imply an intent to deceive on the part of Defendants. Accordingly, the Court will grant Defendants' motion to dismiss with prejudice.

The Court notes that an amendment to the Patent Act that recently passed the United States Senate and now sits before the House of Representatives contains a provision that would prohibit *qui tam* false marking suits altogether. *See* America Invents Act, S. 23, 112th Cong. § 2(k) (2011)). Obviously, if such a bill was enacted it would moot the instant case. *See id.* §2(k)(2) ("The amendments made by this subsection shall apply to all cases, without exception, pending on or after the date of the enactment of this Act.").

An appropriate Order will issue.

/s/ JOEL A. PISANO United States District Judge

Dated: July 14, 2011